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DISCLOSURE CODE

Approved by the Decision of the Meeting of Members of the Association of International Research-based Pharmaceutical Manufacturers of September 22, 2014 and by the Decision of the Meeting of Members of the Latvian Generic Medicines Association of September 30, 2014

Riga, 2014
(valid since January 1, 2015)

PREAMBLE

Healthcare professionals, healthcare institutions and organisations with whom they work provide the medicinal products manufacturers, wholesalers and pharmacists (hereinafter: pharmaceutical industry) with valuable, independent and expert knowledge derived from their clinical and management experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. Healthcare professionals, healthcare institutions and organisations should be fairly compensated for the legitimate expertise and services they provide to the industry.

Medicines developed by the industry are complex products designed to address the needs of patients and educating healthcare professionals about medicines and the diseases they treat, as well as the benefits to the patients. The pharmaceutical industry can provide a legitimate forum for the education of healthcare professionals and the exchange of knowledge among healthcare professionals and industry.

Association of International Research-based Pharmaceutical Manufacturers (SIFFA) and Latvian Generic Medicines Association (LPMA) believe that interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system. SIFFA and LPMA recognise that interactions between the industry and healthcare professionals can create the potential for conflicts of interest. Consequently, professional and industry associations, including SIFFA and LPMA, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order to continue successful collaboration, self-regulation needs to respond to the evolving demands of the society. In particular, there is a growing expectation that interactions between corporations and society are not only conducted with integrity, but are also transparent. Following the European Union Commission initiative on Ethics & Transparency in the pharmaceutical sector, a multi-stakeholders' platform has adopted a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector" (hereinafter: Guiding Principles).

In line with these "Guiding Principles", SIFFA and LPMA believe that it is critical to the future success of the pharmaceutical industry to respond to society's heightened expectations. SIFFA and LPMA have therefore decided that its existing Code on the Promotion of Medicinal Products (hereinafter: the Code of Ethics) should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between the industry and healthcare professionals, institutions and organisations. SIFFA and LPMA hope that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of the society in all stakeholders and pharmaceutical industry in general.

SIFFA and LPMA believe that the interest of patients and all stakeholders in the transparency of these interactions is compelling. SIFFA and LPMA recognise that disclosure can raise data privacy concerns and seeks to work with healthcare professionals, institutions and organisations to ensure that these concerns are addressed. SIFFA and LPMA nonetheless believe that transparency can be achieved without sacrificing the legitimate privacy interests of healthcare professionals. The legislation should not therefore impose excessive restrictions on disclosure by the pharmaceutical industry.

The Disclosure Code provides for disclosure of information on healthcare professionals, whether directly or indirectly involving healthcare institutions and/or organisations. When deciding how the indirect

information should be disclosed, it is advised to disclose the detailed information at the individual healthcare professional (rather than healthcare institution or organisation) level, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws.

The Disclosure Code imposes obligations to disclose information on healthcare professionals, healthcare institutions and organisations commencing with reporting in 2016 for the calendar year 2015. The provisions of this Code shall be implemented in a manner consistent with applicable competition and data protection laws and regulations and all other applicable legal requirements.

APPLICABILITY OF THIS CODE

The Disclosure Code governs disclosures regarding certain collaboration with healthcare professionals (HCPs) and healthcare institutions and organisations (HCOs). It is intended that the Disclosure Code shall apply to collaboration with HCPs and HCOs to the same extent as the existing Code of Ethics. Therefore, the Disclosure Code applies to the Pharmaceutical industry, including, but not limited to (i) SIFFA and LPMA full members: manufacturers of medicinal products developing and manufacturing original and/or generic medicinal products for human use (called *"corporate members"* or "*affiliate corporate members*"); and (ii) other stakeholders of the Pharmaceutical industry, including pharmaceutical companies operating in a particular segment of the pharmaceutical market.

The Disclosure Code sets out the minimum standards which SIFFA and LPMA consider must apply in Latvia, except where its provisions are in conflict with applicable Latvian laws or regulations, in which case deviations from the Disclosure Code are allowed, but only to the extent necessary to comply with such law or regulation of the Republic of Latvia.

Where SIFFA and LPMA have determined that the Disclosure Code cannot be implemented in Latvia in full due to laws or regulations of the Republic of Latvia, SIFFA and LPMA documents the legal issues limiting full implementation of the Disclosure Code. It is understood that if there is an inconsistency between the Disclosure Code and the applicable laws or regulations to which a definite entity (hereinafter: Member Company) is subject and which would make adherence in full to the Disclosure Code not reasonably possible, the Member Company must comply with legislation of its country. Such lack of full adherence to the Disclosure Code shall not constitute a breach of the Disclosure Code.

Member Companies operating under Latvian legislation shall be bound by this Disclosure Code only.

Non- SIFFA and LPMA member entities that decide to voluntarily implement this Disclosure Code shall ensure that despite the legal status of the entity all provisions of the Disclosure Code will be observed.

ARTICLE 1
DISCLOSURE OBLIGATION

Section 1.01. *General Obligation.*
Subject to the terms of Disclosure Code, each Member Company shall document and disclose Transfers of Value it makes, directly or indirectly, to a healthcare professional, healthcare institution or organisation, where the healthcare professionals are working and/or acting (hereinafter: Recipient), as described in more detail in Article 3.

Section 1.02. *Excluded Disclosures*.
Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; or (ii) are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and an HCP (such as a pharmacist) or an HCO; or (iii) in cases not mentioned in Article 3 hereof, e.g. items of medical utility *(provided by the Article 9 of EFPIA HCP Code of Practice)*, meals and drinks (*provided by the Article 10 of the EFPIA HCP Code of Practice, particularly Section 10.05),* medicinal products samples (*provided by the Article 16 of the HCP Code of Practice)* do not fall within the scope of the disclosure obligation described in Section 1.01.

Section 1.03. *Schedules.*
Each of the attached Annexes forms an integral part of the Disclosure Code (hereinafter: Annexes). Definitions of terms are included in Schedule 1 to ensure consistent understanding of such terms.

ARTICLE 2
FORM OF DISCLOSURE

Section 2.01. *Annual Disclosure Cycle.*
Disclosures shall be made every year for a full previous calendar year (hereinafter: the Reporting Period). The first Reporting Period shall be the calendar year 2015.

Section 2.02.*Time of Disclosure.*
Disclosures for the relevant Reporting Period shall be made by each Member Company within 6 months after the end of the relevant Reporting Period. The information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with Section 2.04 of the Disclosure Code, unless, in each case, (i) a shorter period is required under applicable data privacy or other laws or regulations of the Republic of Latvia, or (ii) the Recipient's consent relating to a specific disclosure has been revoked in relation to applicable national law or regulation.

Section 2.03.*Template.*
Subject to Section 2.04(ii), for consistency purposes, disclosures shall be made using a standardised template set forth in Annex 2, reflecting the requirements of the Disclosure Code. Deviations from this List shall be acceptable only in cases when the legislation justifies complete non-implementation of this Code. In such case, only one template shall be used in the definite country.

Section 2.04. *Platform of Disclosure.*
Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available, and, so far as possible, using a template set forth in Annex 2:
(i) on a common data base provided by SIFFA and/or LPMA;
or
(ii) on the Member Company's website in accordance with Section 2.05;
or
(iii) in the common database provided by the relevant governmental institutions, regulatory or

professional institutions.

Section 2.05. *Applicable National Code*.
Disclosures shall be made pursuant to the national Disclosure Code of the country where the Recipient actually lives or is registered. If a Member Company, its affiliate or contractor are not residents in the country where the Recipient actually lives or is registered, the Member Company shall disclose such Transfer of Value in accordance with the Disclosure Code.

Section 2.06. *Language of Disclosure.*
Disclosures shall be made in Latvian. Member Companies can make disclosures not only in Latvian, but also in English.

Section 2.07. *Documentation of Information and Retention of Records*.
Each Member Company shall document Transfers of Value pursuant to Section 1.01. Relevant records made in relation to the Disclosure Code shall be maintained for a minimum of 5 years after the end of the Reporting Period, unless a shorter period is required under applicable data privacy or other laws or regulations.

ARTICLE 3
INDIVIDUAL AND AGGREGATE DISCLOSURE

Section 3.01. *Individual Disclosure.*
Except cases expressly provided by the Disclosure Code, Transfers of Value shall be disclosed on an individual basis about each Recipient. Each Member Company shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

1. *For Transfers of Value to an HCO, an amount related to any of the categories set forth below*:
a. Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations, grants and allowances to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (as governed by Article 12 of the Code of Ethics).
b. Contribution to costs related to Events. Contribution to costs related to Events, including direct donations to HCPs or through HCOs to attend Events, such as:
i. Registration fees;
ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event;
iii. Travel and accommodation (*to the extent governed by Article 10 of the Code of Ethics*).
c. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and institutions, organisations or associations of HCPs under which such institutions, organisations or associations provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. *For Transfers of Value to an HCP*:
a. Contribution to costs related to Events. Contribution to costs related to Events, such as:
i. Registration fees;
ii. Travel and accommodation (*to the extent governed by Article 10 of the Code of Ethics*).
b. Fees for Service and Consultancy. Transfers of Value resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to aMember Companies (or any other type of funding not covered in the previous categories). Fees, on the one hand,

and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

Section 3.02. *Aggregate Disclosure.*
For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.01, cannot be disclosed on an individual basis for legal reasons, a Member Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to Transfers of Value to such Recipients.

Section 3.03. *Non Duplication.*
Where a Transfer of Value required to be disclosed pursuant to Section 3.01 or 3.02 is made to an individual HCP indirectly via an HCO, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made pursuant to Section 3.01(2).

Section 3.04. *Research and Development Transfers of Value.*
Research and Development Transfers of Value in each Reporting Period shall be disclosed by each Member Company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

Section 3.05. *Methodology.*
Each Member Company shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category, as described in Section 3.01. The note shall describe the recognition applied for particular methodology, and should include information on the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value. It shall be done to reach the aims of the Disclosure Code.

ARTICLE 4
ENFORCEMENT

Section 4.01. *Enforcement of the Disclosure Code.*
The Disclosure Code sets out the minimum requirements applicable to Member Companies, except where it is in conflict with applicable laws or regulations of the Republic of Latvia, in which case deviations from the Disclosure Code are allowed, but only to the extent necessary to comply with such laws or regulations.

Section 4.02. *Disclosure Requirements Different from the Disclosure Code.*
Any proposal to amend the Disclosure Code or update any provision of the Disclosure Code, that requires disclosures different from those required under the Disclosure Code, shall be clearly and conspicuously identified in consultative process and supplemented by respective documents confirming such proposal. In such case, the SIFFA and LPMA members meetings shall be asked to confirm consistency with the Disclosure Code following the Board decision taken after consultation with the Ethics Committee.

If the applicable law or regulation, or other industry self-regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member Company shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of the Disclosure Code.

Section 4.03. *Sanctions.*
Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated cases of similar or different offences.

Where a publication of the violation or fines are not permitted, the best alternative effective sanction should be imposed.

Section 4.04. *Reporting*.
Where the information is disclosed only on the Member Company's website, the Ethics Committee shall be notified within one month of the information disclosure by sending the relevant website address of the Member Company.

ARTICLE 5
AMENDMENTS TO THE DISCLOSURE CODE AND GUIDANCE REGARDING COMPLIANCE WITH THE DISCLOSURECODE

Section 5.01. *Amendments to the Code.*
The Ethics Committee shall review provisions of the Disclosure Code and any documents related to the Disclosure Code, if necessary, following consultation with the SIFFA and LPMA membership.

Any proposed amendments to the Disclosure Code shall be submitted for SIFFA and LPMA Board decision and the SIFFA and LPMA members meeting ratification.

ARTICLE 6
RECEIPT OF COMPLAINTS, EXAMINATION AND SANCTIONS

Section 6.01. *Receipt of complaints, examination and sanctions.*
Receipt of complaints, their examination and determination of sanctions is performed in accordance with the "Procedure for examination of complaints and implementation of sanctions".

Annex 1 to the Disclosure Code

TERMS USED

Donations and Grants
Donations and Grants, collectively, means those donations and grants (either cash or benefits in kind) provided within the scope of Article 11 of the Code of Ethics.

Events
All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning and training of investigator meetings for clinical trials and non-interventional studies) (each, an "Event") organised or sponsored by or on behalf of an organisation.

HCO
Any legal entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other educational institution or training group (except for patient organisations) or (ii) through which one or more HCPs provide services.

HCP
Any natural person that is a representative of the medical, dental, pharmacy or nursing profession or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply or dispense a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or dispense medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of medicinal products.

Medicinal Products
(a) Any substances or combination of those having an effect of treating or preventing human diseases; or (b) any substances or combination of those that can be prescribed to humans in order to restore, improve or change physiological functions, and that exhibit pharmacological, immunological or metabolic effect, or to make a medical diagnosis (*as amended by Article 1 of the Council Directive 2001/83/EC*).

Recipient
Any HCP or HCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

Research and Development Transfers of Value
Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in *OECD Principles on Good Laboratory Practice*); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data for any study performed by one or several HCPs (Section 16.02 of the Code of Ethics).

Transfers of Value
Direct or indirect transfers of value, whether in cash or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or original prescription-only medicinal products for human use. Direct transfers of value are those made directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient by the third party (like contractors, agents, partners of affiliates (including foundations)) and where the identity of such Member Company is known to the Recipient or can be identified.

Annex 2 to the Disclosure code

Schedule 2 - TEMPLATE *Article 2 - Section 2.03*														
		Full Name *(Art. 1.01)*	HCPs: City of Principal Practice HCOs: city where registered *(Art. 3)*	Country of Principal Practice *(Schedule 1)*	Principal Practice Address *(Art. 3)*	Unique country local identifier *OPTIONAL* *(Art. 3)*	Donations and Grants to HCOs *(Art. 3.01.1.a)*	Contribution to costs of Events *(Art. 3.01.1.b & 3.01.2.a)*		Fee for service and consultancy *(Art. 3.01.1.c & 3.01.2.c)*		Transfers of Value re Research & Development as defined *(Art. 3.04)*	TOTAL *OPTIONAL*
								Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract		
INDIVIDUAL	HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP** (i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
		Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	
		***OTHER, NOT INCLUDED ABOVE** - where information cannot be disclosed on an individual basis for legal reasons*												
		Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate)* - *Art. 3.02*					N/A	N/A	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of total transfers of value to individual HCPs - *Art. 3.02*					N/A	N/A	%	%	%	%	N/A	N/A
	HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO** (i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
		HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	N/A	*Optional*
		***OTHER, NOT INCLUDED ABOVE** - where information cannot be disclosed on an individual basis for legal reasons*												
		Aggregate amount attributable to transfers of value to such Recipients - *Art. 3.02*					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	N/A	*Optional*
		Number of Recipients *(named list, where appropriate)* - *Art. 3.02*					*number*	*number*	*number*	*number*	*number*	*number*	N/A	*Optional*
		% of total transfers of value to individual HCOs - *Art. 3.02*					%	%	%	%	%	%	N/A	N/A
AGGREGATE		***AGGREGATE DISCLOSURE***												
		N/A	N/A	N/A	N/A	N/A	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*OPTIONAL*	*TOTAL AMOUNT*	*OPTIONAL*

NA – not applicable